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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,650	11/09/2001	Hironori Tomi	44432.013600	6399

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EXAMINER

PATTEN, PATRICIA A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,650

Applicant(s)

Tomi et al.

Examiner

Patricia Patten

Art Unit

1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/02 and 12/13/02
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-46 is/are pending in the application.
- 4a) Of the above, claim(s) 15, 17, 19, and 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 18, 20, and 29-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1654

DETAILED ACTION

Claims 15-46 are pending in the application.

Election/Restriction

Applicant's election with traverse of group II, claims 16, 18, 20-22, 29 and 30 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that there is no 'substantial difference between the effects of the plant and its extract on compromised reproductive function. Both the plant itself, which contains various ingredients, and the extracted ingredients when administered to a human subject in need of such treatment can make compromised reproductive function recover'. This is not found persuasive because as described in the Restriction requirement (part of Paper No. 5, the claims lack a special technical feature under PCT Rule 13.1. Thus, the basis for this restriction requirement lies in the fact that the alleged special technical feature, which is *Withania somnifera* dunal 1) is not found *throughout* the claims, and 2) is not novel over the prior art (*Withania somnifera* is a known natural plant material). In order to fulfil the requirements of possessing a special technical feature, the alleged 'special technical feature' must be novel over the prior art.

Art Unit: 1654

It is further noted that claim 21 was inadvertently examined in the previous Office Action as if it were drawn to claim 20. Claim 21 is actually dependant upon claim 19, which is a non-elected claim. Therefore, claim 21 has also been withdrawn from examination on the merits as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16, 18, 20, and 29-46 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 16, 18, 20 and 29-46 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1654

Claims 16, 18, 20 and 29-46 either recite, or depend upon a claim which recites 'wherein the extract contains not less than 1 wt % of alkaloids and not less than 1 wt % withanolides'. This information is not found within the Instant specification as filed and is therefore considered New Matter. It is noted that the claims were examined on the merits as they stand, containing the New Matter.

Applicant is required to remove the New Matter from the claim in order to overcome this rejection.

Claims 16, 18, 20, 21, 29 and 30 remain rejected, and new claims 31-40 and 42-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition/method comprising an ethanol or water extract of *Withania somnifera* for increasing sperm count, does not reasonably provide enablement for a composition/method comprising an ethanol or water extract *W.sominifera* for restoring any type of compromised reproductive function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Art Unit: 1654

Applicants argue that Garg et al. is not an appropriate reference to support the rationale for this rejection (p.7-Arguments). Applicants state that Garg et al. used a different sub-set of mice, specifically, normal mice in comparison to mice with compromised reproductive function as shown in the Instant specification, and further because Garg et al. fed their mice root powder of *W.somnifera*, while the Instant claims recite an aqueous/alcoholic extract (as recently amended).

The differences between the Garg et al. reference and the Instant specification are duly noted. However, the Garg et al. reference was cited to support the contention that the state of the art was unpredictable with regard to methods for treating fertility problems with *W.somnifera* at the time the Invention was made and to support the rationale that Applicants have not provided the skilled artisan enough information to use the invention within the broad scope of the claims.

Abdel-Magied et al. additionally reported that although the water extract of *W.somnifera* increased sperm count, it also caused "...paucity of the sustentacular Sertoli cells" (p.3). Abdel-Magied et al. explained that the Sertoli cells protected spermatogenic cells from harmful substances (p.3).

The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. As it was

Art Unit: 1654

discussed in the previous Office Action, Applicants have not demonstrated that *W.somnifera* has any effect on male reproductive function. Consequently, there is no working example that would clearly indicate that an extract of *W.somnifera* would actually perform within the scope of the Instantly claimed invention, even with regard to male mice and especially in humans. Drawing to the prior art to provide some predictability for the scope of the claimed Invention, a reference was found that indicates that mice which were fed powdered *W.somnifera* had decreased fertility (Garg et al.). Applicants argue that Garg et al. did not administer extracts, but administered powdered root of *W.somnifera*. As discussed *supra*, this is agreed upon. However, because the powder of *W.somnifera* inherently contains the phytochemicals produced by an extraction of the same plant matter, the artisan would have expected *at least some* beneficial outcome with regard to increased male fertility if the extract of the root was alleged to possess this pharmacological property. On the contrary, Garg et al. reported that administration of powdered *W.somnifera* *actually decreased fertility in male, as well as female mice.*

Applicants have not provided any evidence in the amendment which would lead the Examiner to conclude that the composition of the Instant invention actually works within the scope of the claimed invention, especially in light of the unpredictability in the

Art Unit: 1654

art and the lack of working examples in the Instant specification (*supra*). Thus, the rejection stands.

Claim Rejections - 35 USC § 102

Claims 16, 18, 20 remain rejected, and new claims 31, 34, 35, 38, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Chavali et al. (US 5,683,698).

Applicants' arguments were fully considered, but not found persuasive.

The Applicant states that, "The Examiner's interpretation of the Chavali reference is ...incorrect". (P.10-Arguments). Applicants' principal argument pertaining to this rejection is that the Chavali reference requires a mixture (combination) of extracts of herbs to reduce and alleviate arthritis.

First, it is deemed that, and admitted by Applicants, that the extracts disclosed by Chavali were aqueous extracts. These claims specifically recite 'aqueous or alcohol' extract. Although the claims also recite 'wherein the extract contains not less than 1 wt % of alkaloids and not less than 1 wt % of withanolides', this is considered an inherent

Art Unit: 1654

property of the composition: The product *must be the same if the steps for preparing are the same*:

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are **produced by identical or substantially identical processes**, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Here, Chivali disclosed that the water extract of *W.somnifera* was administered to patients for treating arthritis. Although the extract was in a mixture, Applicant is reminded the claims state 'comprising' which is open language. Because the claims state 'comprising' the composition and method claims can incorporate additional ingredients/steps.

With regard to the composition claims, the phrase 'for restoring compromised reproductive function' is considered an intended use of the product which doesn't hold much patentable weight. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

Art Unit: 1654

Claim 16 remains rejected and claims 32, 33, 34, 36, 37, 39, 40, 43, 44, 45 and 46 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (1978).

Applicants' arguments were fully considered, but not found persuasive.

Applicants argue that Rao et al. does not meet the requirements of 35 USC 112 First paragraph and thus contend that Rao et al. does not anticipate the claimed invention. Applicants state that "Each extract in turn is a different product from the *W.somnifera* powder disclosed in Rao..." (P.10 -Arguments). Applicant additionally cites Revilla (1998) and states that Rao's disclosure is insufficient to allow a skilled artisan to make and use the products disclosed". The Examiner respectfully disagrees. Although the Rao et al. reference is brief, it indeed includes the critical elements to make and use their product. Rao et al. specifically teach that the roots of *W.somnifera* were extracted with ether and ethanol and were administered to male rats. One of ordinary skill in the art would know how to make an ether extract of *W.somnifera* and an ethanol extract of *W.somnifera* because the procedures for extracting plant material with these types of solvents was routine in the art at the time of the Rao et al. reference. Certainly, the ordinary artisan would know how to administer the extracts to the rats, because Rao et al. specifically taught that the products were fed intraperitoneally to the male rats.

Art Unit: 1654

It is again noted that the intended use of the composition claims do not materially change the composition (*supra*). Further, the method claims merely state administration to a male subject, which is anticipated by Rao et al. since they administered the extracts to male mice.

No Claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Application/Control Number: 10/031,650

Art Unit: 1654

Page 11

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER R. TATE
PRIMARY EXAMINER